



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 19 2010

Re: ONGLYZA
Docket No.: FDA-2010-E-0061

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the application for patent term extension for U.S. Patent No. 6,395,767, filed by Bristol-Myers Squibb Company, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for ONGLYZA (saxagliptin), the human drug product claimed by the patent.

The total length of the regulatory review period for ONGLYZA (saxagliptin) is 2,794 days. Of this time, 2,397 days occurred during the testing phase and 397 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: December 8, 2001.

The applicant claims November 8, 2001, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 8, 2001, which was 30 days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: June 30, 2008.

FDA has verified the applicant's claim that the new drug application (NDA) for ONGLYZA (NDA 22-350) was submitted on June 30, 2008.


3. The date the application was approved: July 31, 2009.

FDA has verified the applicant's claim that NDA 22-350 was approved on July 31, 2009.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Jane A. Axelrad". The signature is fluid and cursive, with a long horizontal stroke at the end.

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Kevin E. Noonan
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